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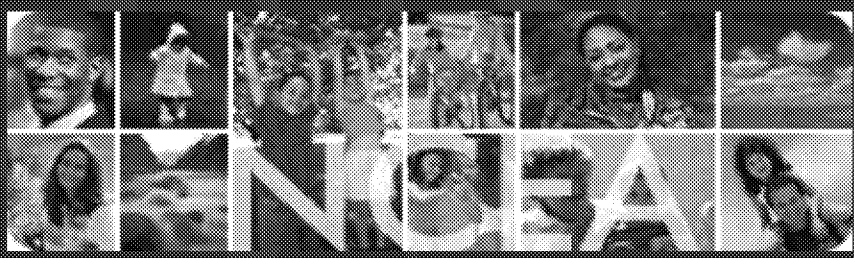
The National Center for Environmental Assessment (NCEA)

EPA's Integrated Risk Information System (IRIS)

Becki Clark
Acting Director, National Center for Environmental Assessment



Office of Research and Development
National Center for Environmental Assessment

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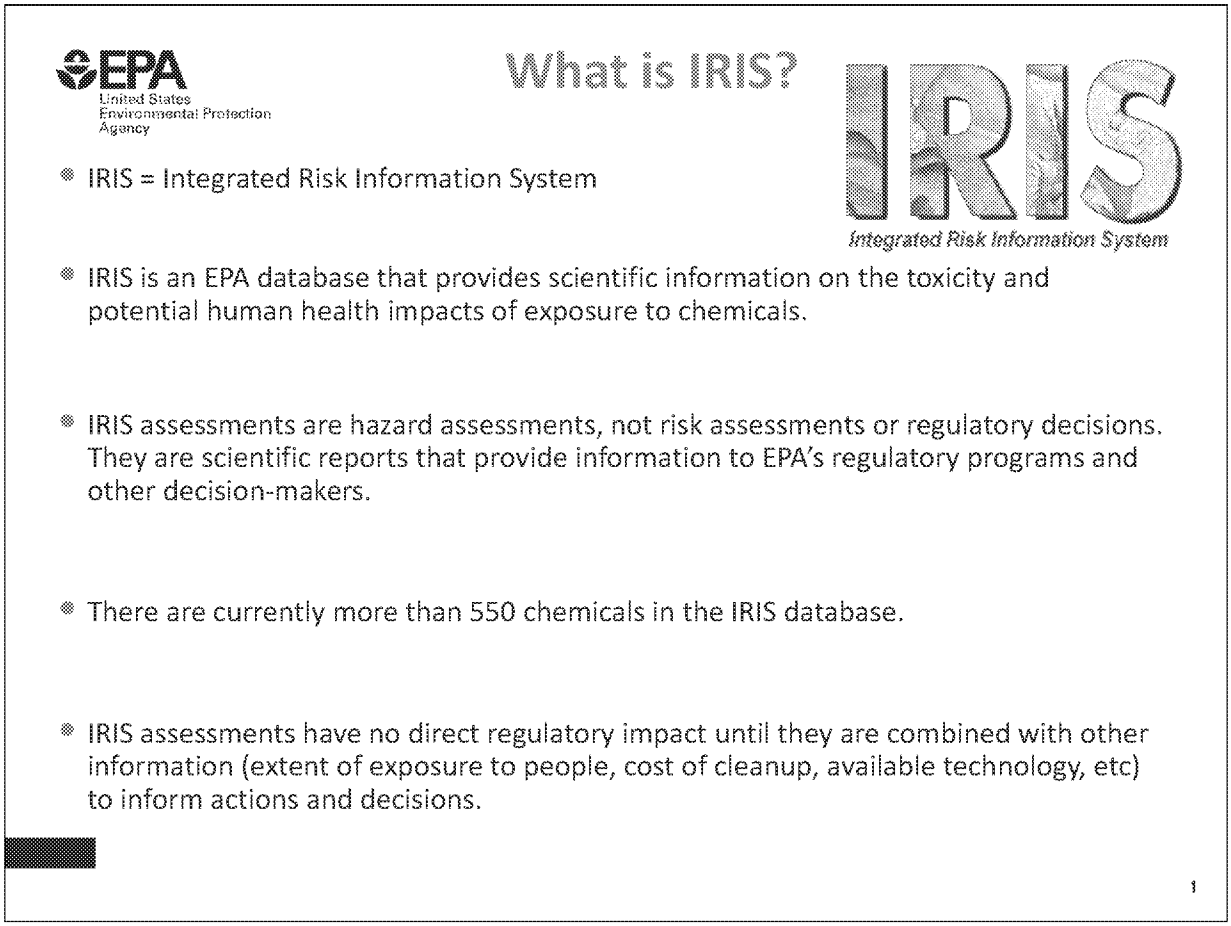


Provides EPA scientific positions on potential adverse health effects that may result from exposure to chemical substances found in the environment

Oral reference doses and inhalation reference concentrations for non-cancer endpoints

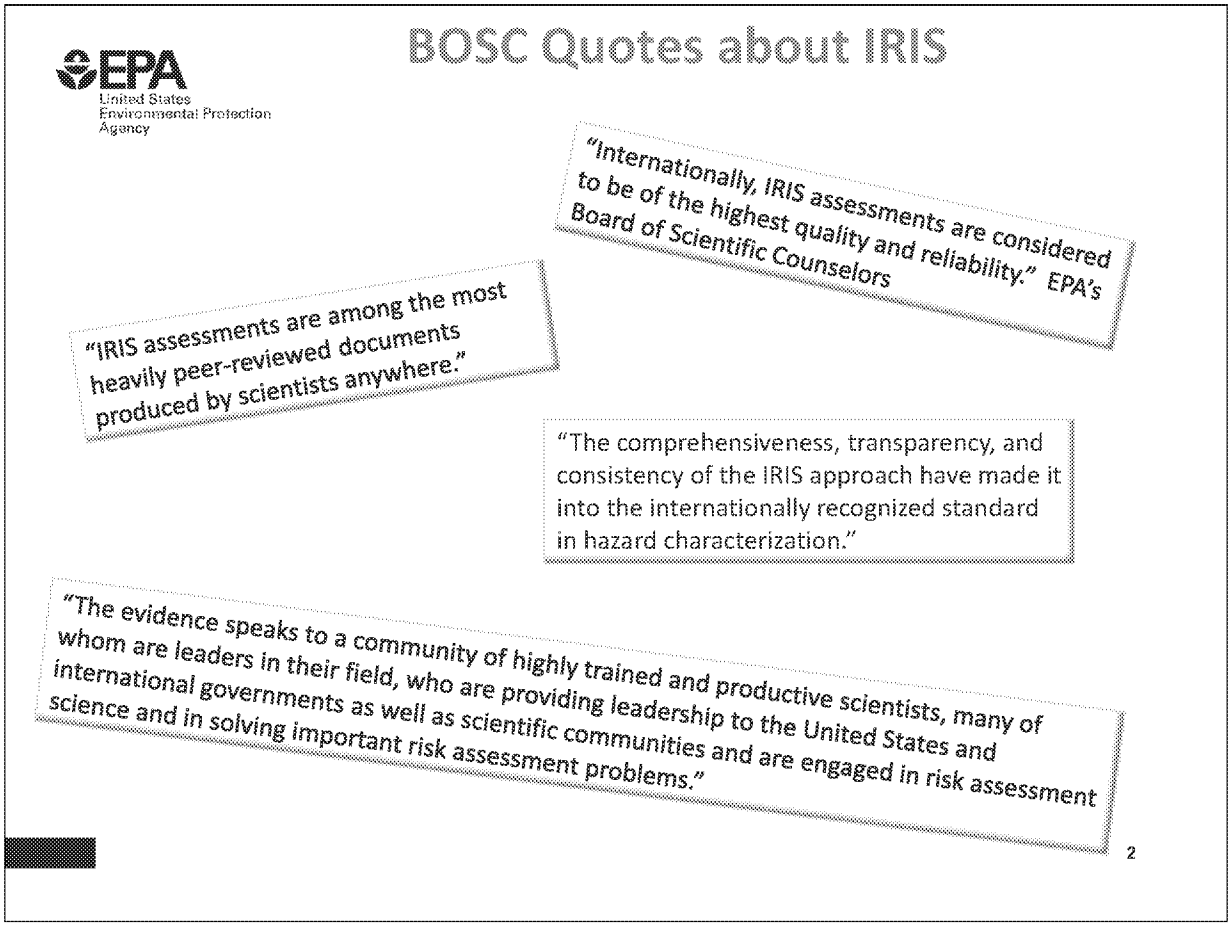
A weight of evidence description (e.g., known human carcinogen), oral slope factors, and inhalation unit risks for cancer

EPA risk assessors combine IRIS toxicity values with scenario-specific exposure values to estimate risk

Source of toxicity information to inform risk-based decision-making; founded on EPA guidelines for health risk assessment

Fosters consistent risk assessments across EPA Programs and Regions

Support NAS risk assessment paradigm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BOSC Quotes about IRIS
"Internationally, IRIS assessments are considered to be of the highest quality and reliability." EPA's Board of Scientific Counselors
"IRIS assessments are among the most heavily peer-reviewed documents produced by scientists anywhere."
"The comprehensiveness, transparency, and consistency of the IRIS approach have made it into the internationally recognized standard in hazard characterization."
"The evidence speaks to a community of highly trained and productive scientists, many of whom are leaders in their field, who are providing leadership to the United States and international governments as well as scientific communities and are engaged in risk assessment science and in solving important risk assessment problems."
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What is included in an IRIS Assessment?

Depending on what data are available, IRIS assessments may include information on:

- The amount of a chemical that people can be exposed to daily without facing an appreciable risk of harmful health effects other than cancer
- The potential for a chemical to cause cancer in people
- The estimated carcinogenic risk people face from exposure to a chemical over the course of a lifetime (oral and/or inhalation).

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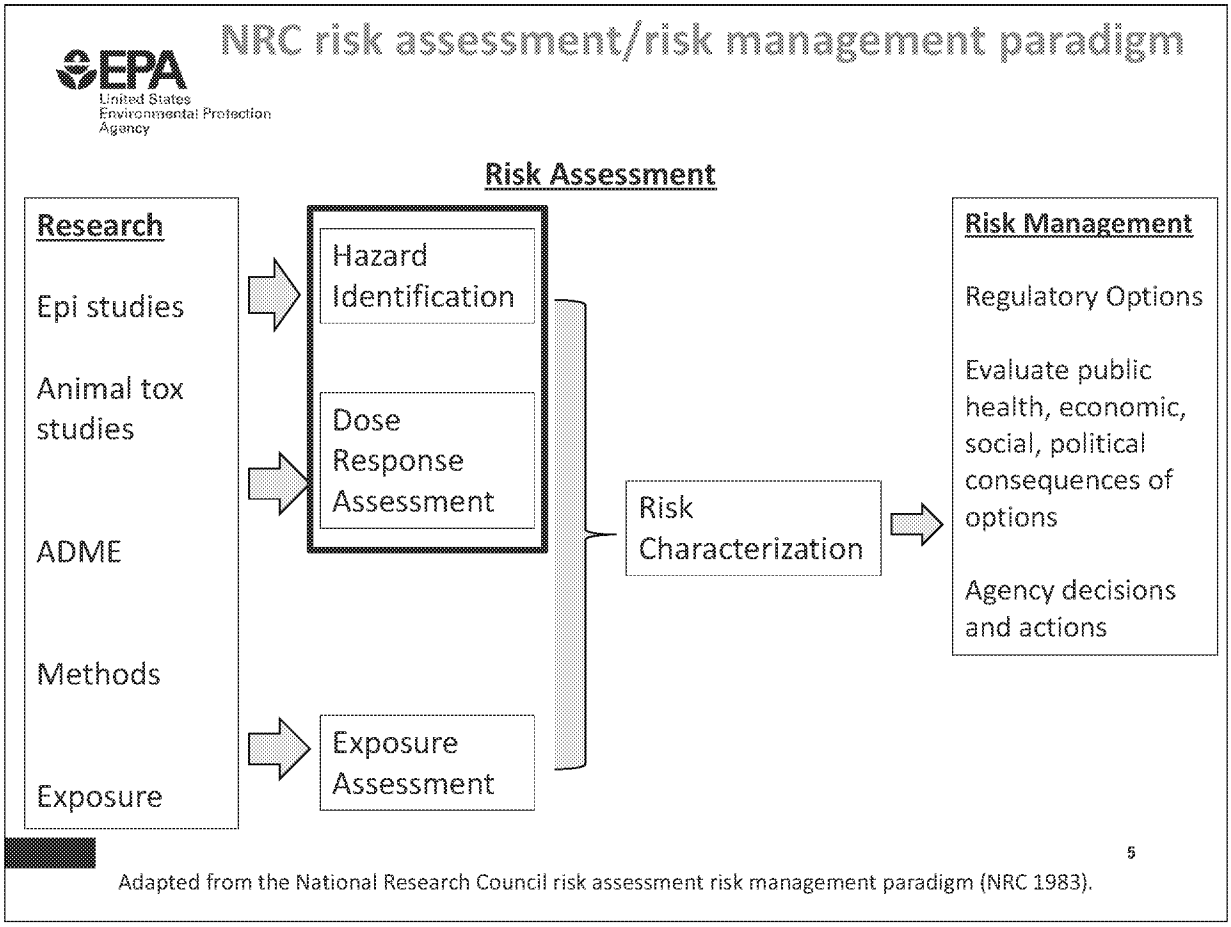
What IRIS is not

As stand-alone scientific documents, IRIS assessments are not:

- Risk assessments
- Risk management decisions
- Regulations
- Policy documents
- Guidance documents

Re-evaluation of past IRIS assessments using the latest scientific data does not always lead to more stringent hazard information. This only occurs in about half of re-evaluations.


NRC risk assessment/risk management paradigm
United States Environmental Protection Agency
Risk Assessment
Research
Epi studies
Animal tox studies
ADME
Methods
Exposure
Hazard Identification
Dose Response Assessment
Exposure Assessment
Risk Characterization
Risk Management
Regulatory Options
Evaluate public health, economic, social, political consequences of options
Agency decisions and actions
5
Adapted from the National Research Council risk assessment risk management paradigm (NRC 1983).

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Who Uses IRIS?

- EPA's Program Offices and Regions
- States
- Local health agencies
- International organizations
- Other federal agencies

EPA's Programs and Regions partner with ORD to set the agenda for IRIS.

GAO Activities Related to IRIS

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March 2008 — GAO issues report on IRIS, stating that low productivity and interagency process limit the usefulness and credibility of IRIS.

April 2008 — EPA issues a revised IRIS process.

April 2008 – September 2008 — GAO testifies before Congress three times indicating that the new assessment process further limits the productivity and credibility of the IRIS program.

January 2009 — GAO issues biannual High Risk Report. IRIS is included.

May 21, 2009 — EPA issues a revised IRIS process that addresses the process recommendations from GAO in their March 2008 report and 2008 testimony.

February 2011 — GAO issues biannual High Risk Report. IRIS remains a high risk area.

December 2011 — EPA received a new GAO report on IRIS noting that improvements have been made, but challenges remain with IRIS.

Summary of March 2008 GAO Report

United States Environmental Protection Agency

GAO recommended that EPA reevaluate IRIS assessment process and ensure that any revised process:

- Can be conducted within time frames that minimize need for rework and considers trade-off between benefits of changes that involve additional steps/time (e.g., enhanced uncertainty analyses) and impacts of these changes on ability to complete timely assessments;
- Establishes a policy that endorses conducting IRIS assessments on the basis of peer-reviewed scientific studies available at the time of the assessment and develops criteria for allowing assessments to be suspended to await the completion of scientific studies only under exceptional circumstances;
- Establishes IRIS assessment needs to provide at least 2 years' notice of assessments that are planned, including criteria for making exceptions to the advance notifications, if needed;
- Sets time limits for all parties, including OMB and other federal agencies, to provide comments on draft IRIS assessments;
- Periodically assesses the level of resources that should be dedicated to the program to meet user needs and maintain a viable IRIS database; and
- Better ensures that EPA has the ability to develop transparent, credible IRIS chemical assessments—an ability that relies in large part on EPA's independence in conducting these important assessments.

Summary of March 2008 GAO Report (continued)

United States Environmental Protection Agency

GAO indicated that actions that are key to this ability include ensuring that EPA:

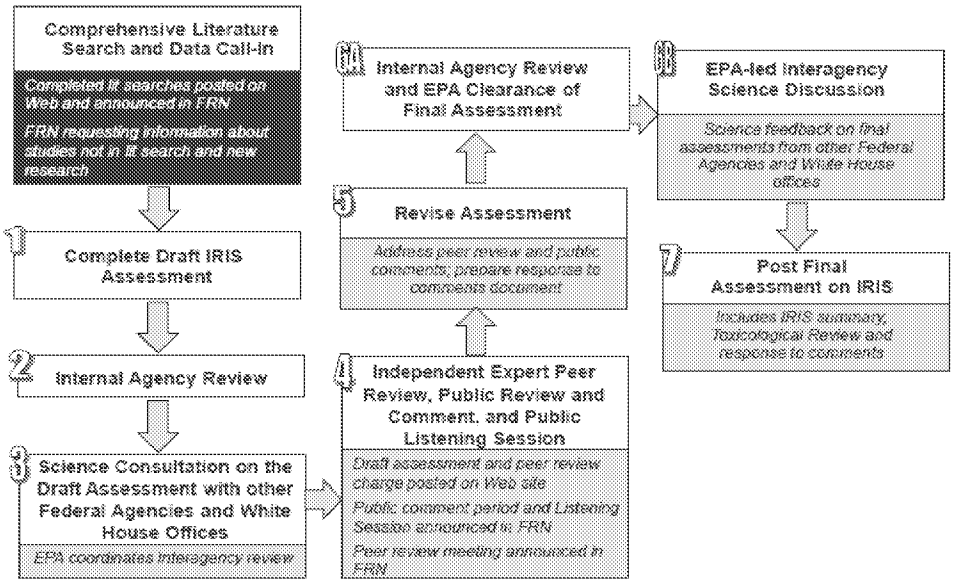
- Can determine the types of IRIS assessments to conduct on the basis of the needs of EPA's program offices and other users;
- Can define the appropriate role of external federal agencies in the IRIS assessment process and manage an interagency review process in a manner that enhances the quality, transparency, timeliness, and credibility of IRIS assessments, including determining when interagency issues have been appropriately addressed; and
- Has the ability to provide comments by OMB and other federal agencies on draft IRIS assessments to decision makers, the Congress, and the public.

In addition to these process related recommendations, GAO also highlighted six key IRIS assessments – naphthalene, Royal Demolition Explosive (RDX), formaldehyde, trichloroethylene, tetrachloroethylene, and dioxin – that have been delayed by the concerns they noted.

IRIS Process since May 2009 – Developed in Response to GAO Recommendations

United States Environmental Protection Agency

Assessment Development Process for New IRIS



Additional Improvements since May 2009

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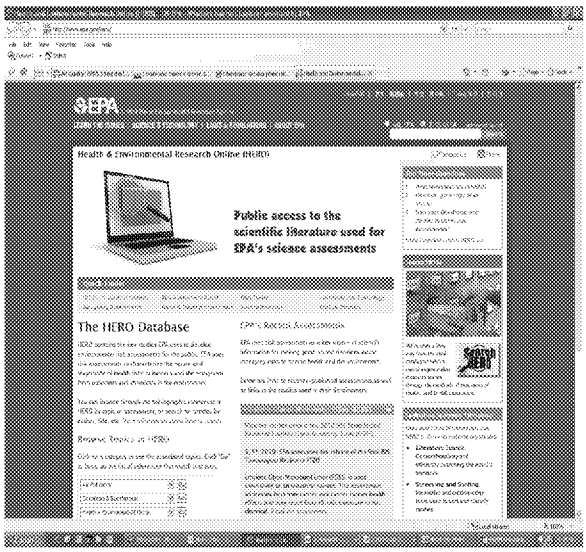
Since May 2009, EPA has continued to improve IRIS:

- Extended role of EPA's program and regional offices in nominating and prioritizing chemicals for assessment to ensure IRIS focuses on most critical Agency needs.

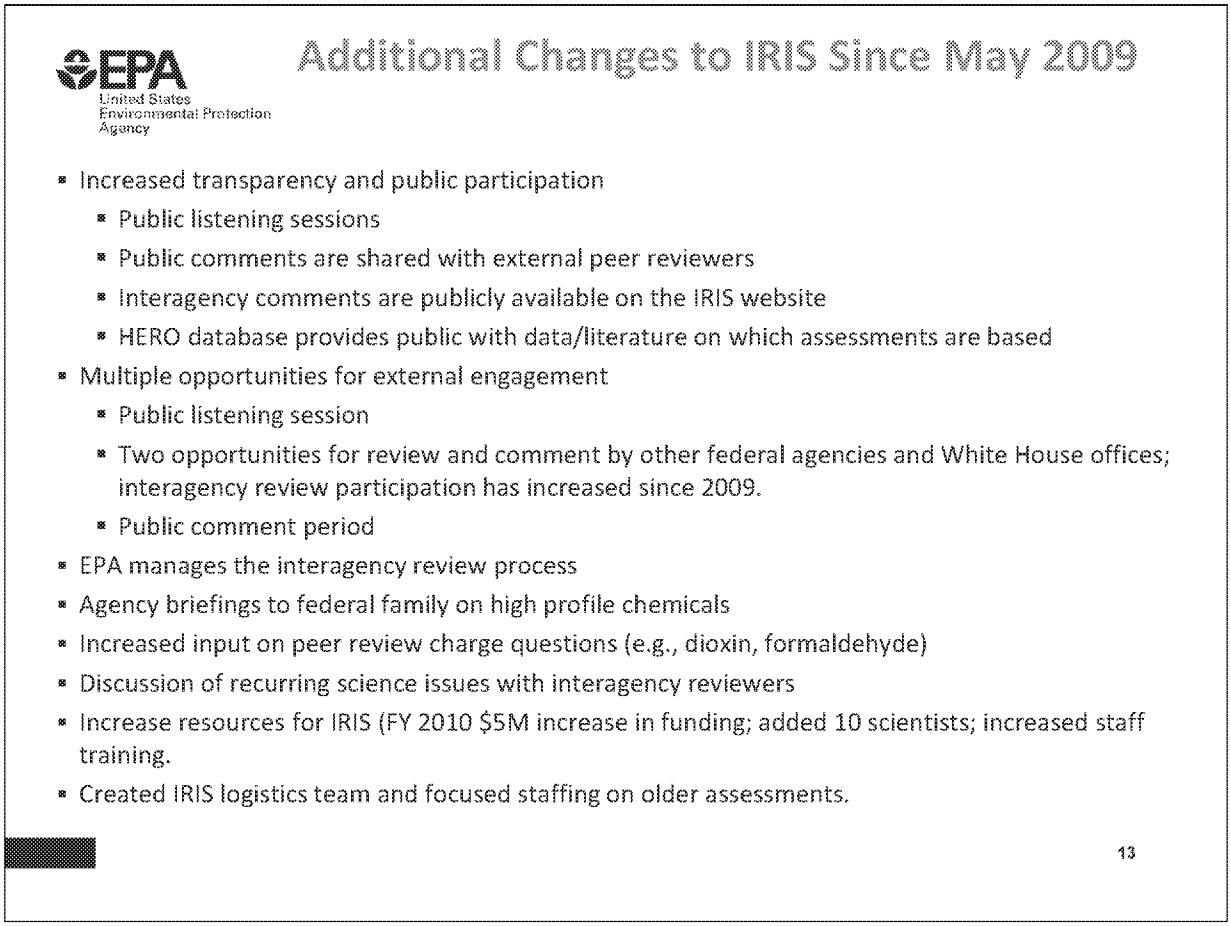
- Health and Environmental Research Online – or HERO – database to promote transparency by capturing the scientific literature used in Agency health and environmental assessments and making the scientific studies selected and used by the Agency to develop assessments available to the public.

Innovation with Health and Environmental Research Online (HERO) Database

- HERO – a database of scientific studies used to develop EPA risk assessments
  - Created for the Integrated Science Assessment Program
  - Expanded to include IRIS and PPRTV assessments as they are developed
  - Allows the public to readily access studies on which decisions are based.
- HERO provides:
  - Citation and abstract
  - Topic areas that describe the reference
  - Assessment for which reference was used
- HERO is an ***EVERGREEN*** database – new studies are continuously added



www.epa.gov/hero



EPA actions since May 2009 have resulted in:
Increased transparency and public participation.
Listening sessions for the purpose of soliciting public and stakeholder comments.
Transmittal of the public comments that were submitted to the public comment docket, to the external peer review panel
Interagency comments are publicly-available via online posting of all Federal Agency review comments and more recently, EPA responses to those comments.
Development of a new online database – Health and Environmental Research Online (HERO) – that offers the public access to the studies on which assessment decisions are based (www.epa.gov/hero).

Recent Accomplishments

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Since the May 2009 process was implemented, EPA has completed 24 final IRIS assessments, including several long-awaited and high profile assessments.

Final assessments recently posted

- Tetrahydrofuran (February 2012)
- Dioxin, noncancer (February 2012)
- Tetrachloroethylene (February 2012)
- Dichloromethane (November 2011)
- Trichloroacetic acid (September 2011)
- Trichloroethylene (September 2011)
- Hexachloroethane (September 2011)
- Urea (July 2011)

Draft assessments recently released for public comment and external peer review

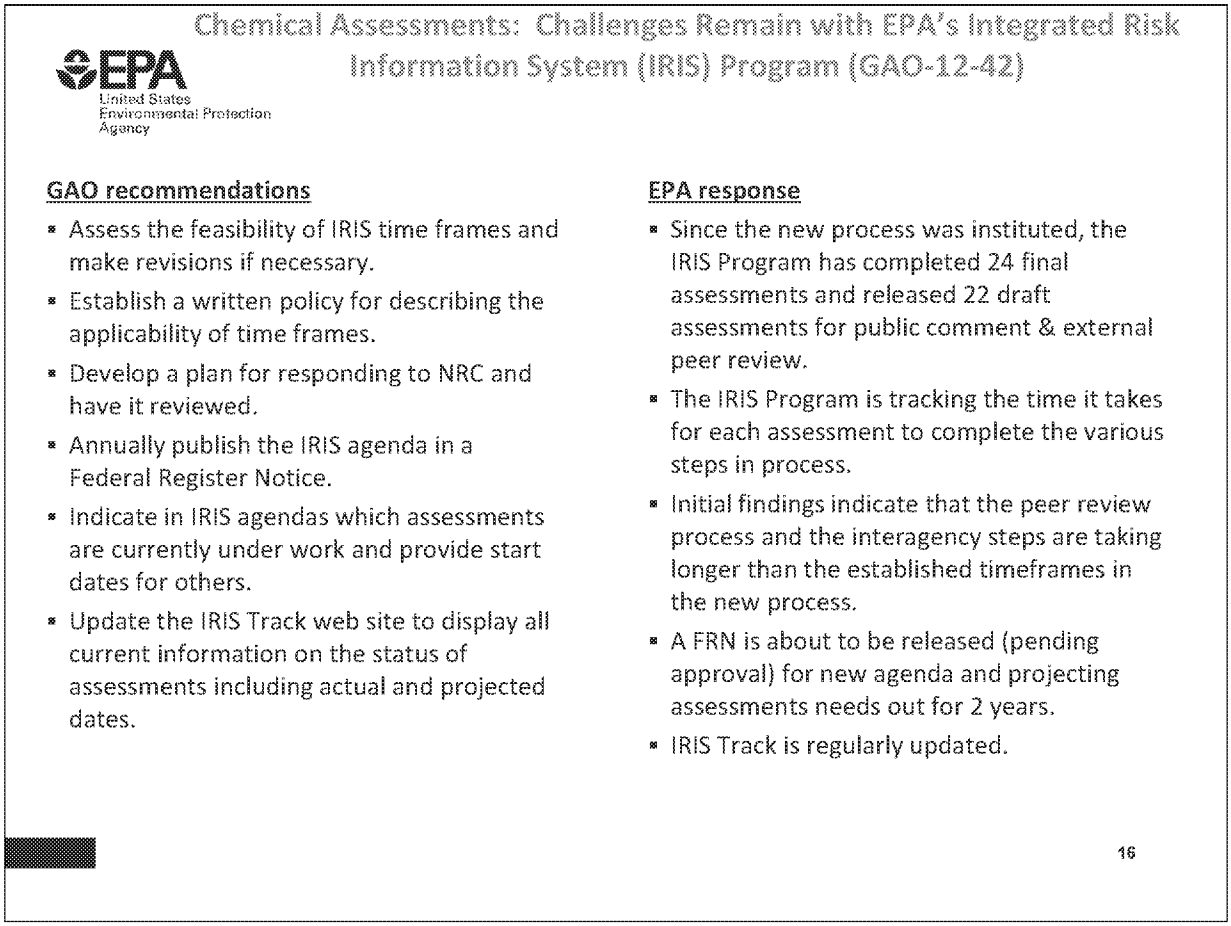
- Biphenyl (September 2011)
- Vanadium pentoxide (September 2011)
- n-Butanol (August 2011)
- 1,4-Dioxane, inhalation (August 2011)
- Libby amphibole asbestos (August 2011)

December 2011 GAO Report on IRIS

United States Environmental Protection Agency

- GAO recognized that EPA has restored control of the IRIS process to the Agency and increased its transparency.

- GAO recommended that EPA:
  - Enhance the timeliness and certainty of timelines in the development of IRIS toxicological reviews;
  - Improve the clarity and transparency of IRIS toxicological reviews; and
  - Improve information to users of IRIS on current and future assessments.



Additionally, GAO raised specific concerns regarding the completion of IRIS assessments for six chemicals – trichloroethylene (TCE), tetrachloroethylene (PERC), dioxin, formaldehyde, RDX and naphthalene.
EPA has recently completed the final IRIS assessment for TCE, PERC and dioxin noncancer. Work is ongoing to complete the IRIS assessments for formaldehyde, RDX, dioxin (cancer) and naphthalene.

Open Recommendations from March 2008 Report

United States Environmental Protection Agency

GAO recommendations	EPA response
• Establish a policy that endorses conducting IRIS assessments on the basis of peer-reviewed scientific studies available at the time of the assessment and criteria for allowing suspension of an assessment only under exceptional circumstances; • Establish IRIS assessment needs to provide at least 2 years' notice of assessments that are planned, including criteria for making exceptions to the advance notifications, if needed; • Periodically assesses the level of resources that should be dedicated to this significant program to meet user needs and maintain a viable IRIS database. • Determine the types of IRIS assessments to conduct on the basis of the needs of EPA's program offices and other users.	• Criteria for suspending an assessment include lack of resources when critical staff leave, congressional mandates & critical new data becomes available that will substantially change the bottom line determination/conclusion of an assessment • Need to post FRN for new chemicals agenda and add criteria for exceptions to the normal nomination process. • Annual budget planning and op planning addresses this recommendation. • Addressed with annual prioritization and nomination followed by quarterly program/ regional engagement updating needs and change in priorities. • Cross walking of TSCA workplan and OPP action plans with IRIS agenda/ nominations and PPRTVs also addresses this effort.

Adding Chemicals to the IRIS Agenda

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- In October 2010, NCEA solicited nominations from EPA Programs and Regions, other federal agencies, and the public; FRN announced the nomination period and included evaluation/decision criteria.
- 60 chemicals or groups of chemicals were nominated.
- Screening literature search performed to determine whether sufficient information exists to develop at least one toxicity value (reference dose, reference concentration, oral slope factor, inhalation unit risk).
- In June 2011, EPA Programs and Regions asked to indicate priorities for nominated chemicals with sufficient data and for inactive IRIS chemicals.
- Chemicals prioritized according to EPA needs and other criteria published in the requests for nominations.
- On February 9, 2011, NCEA briefed the Programs and Regions on this process, including decisions about what chemicals to add to the IRIS agenda.

Proposed New IRIS Assessments for 2012-2014

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Chemical	Who Nominated (if known)	Year assessment will begin
Carbonyl sulfide*	OAR	FY2012
Manganese*	Region 1	FY2013
tert-Amyl methyl ether (TAME), 4,4'-dimethyl-3-oxahexane (TAEE)*	OSWER	FY2013
Diisopropyl ether (DIPE)*	OSWER	FY2013
Isopropanol*	OCSPP	FY2013
Antimony*		FY2013
Chlorobenzene	OSWER	FY2013
Octamethycylcotetrasiloxane (D4), Decamethylcyclotetrasiloxane (D5)	OCHP	FY2013
Vanadium and compounds	OCHP	FY2013
Elemental mercury and methyl mercury	OP	FY2014
Ethylene dichloride*	OAR	FY2014
Tungsten and compounds*	Region 1	FY2014

*Currently on the IRIS agenda, but inactive

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GAO Criteria for Removing EPA from High Risk List

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- **Leadership**: EPA Administrator supports improvements to IRIS and TSCA activities
- **Capacity:** EPA and Congress ensure that resources dedicated to IRIS and TSCA are sufficient to maintain a viable IRIS database and effectively implement TSCA.
- **Corrective Action Plan:** An action plan exists that defines root of cause, solutions and provides for substantially completing corrective measures near term with implementation of GAO recommendations
- **Monitoring and Independent Validation:** Institute program to monitor and independently validate the effectiveness and sustainability of IRIS assessment process and initiatives to use existing TSCA authorities.
- **Demonstrate Progress:** Routinely complete timely, creditable IRIS assessments and initiate new assessments. Show progress toward fully utilizing existing TSCA authorities, identify legislative changes needed and work with Congress to facilitate changes to TSCA.

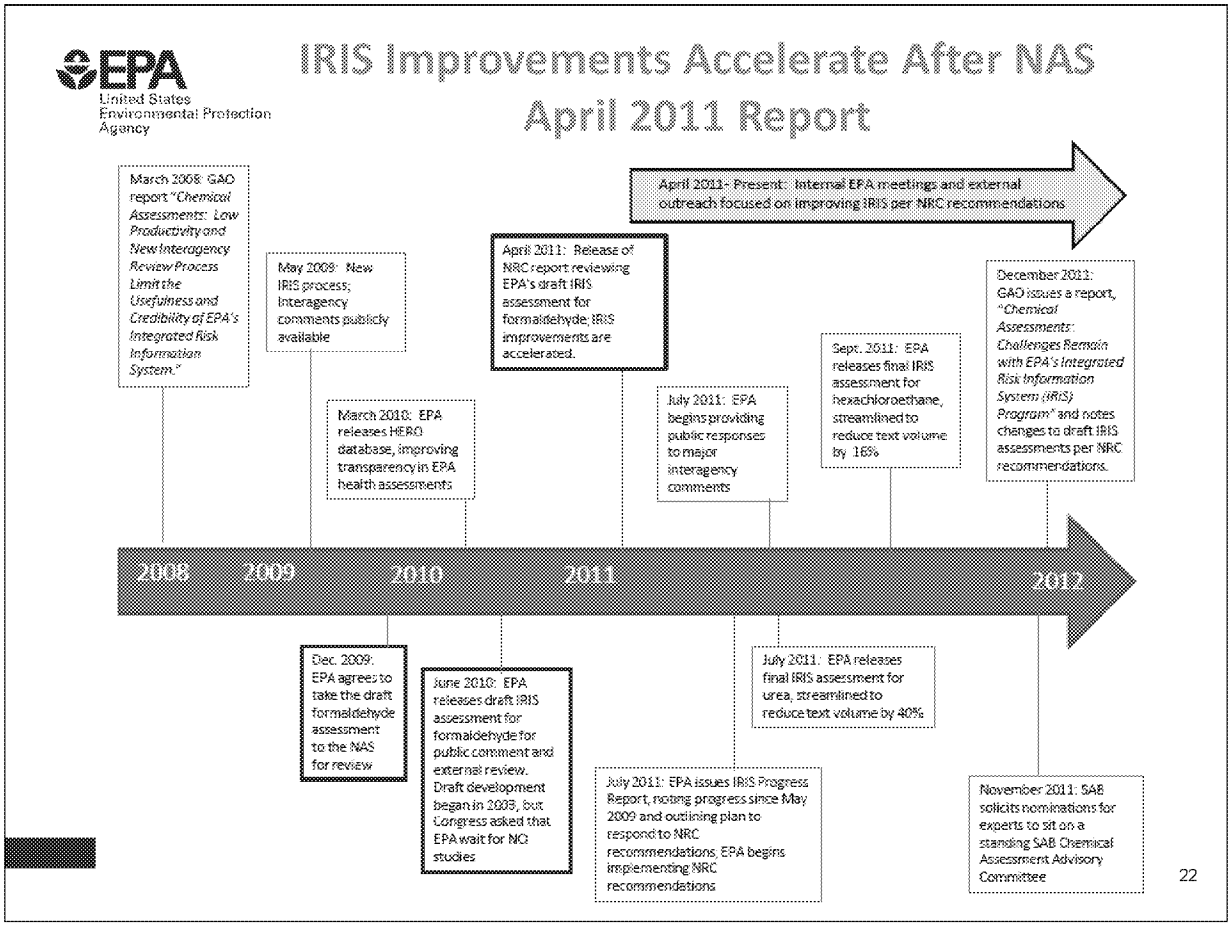
NRDC Report: Strengthening Toxic Chemical Risk Assessments to Protect Human Health – February 2012

United States Environmental Protection Agency

NRDC recommended that EPA and FDA strengthen chemical risk assessments to incorporate key recommendations from the NAS reports *Science and Decisions* and *Phthalates and Cumulative Risk Assessment*. They recommended four main areas of reform:

1. Identify and incorporate variability in human exposure and vulnerability into health assessments, so that all people are better protected.
2. When information is missing or unreliable, use science-based default assumptions that protect health, rather than waiting for more data, to speed up the chemical assessment and decision-making processes. There should be a clear set of criteria for when to depart from default assumptions.
3. In assessing the risk of chemicals, incorporate information about the potential impacts of exposure to multiple chemicals. Consider other factors, such as exposure to biological and radiological agents, and social conditions.
4. Because the population is exposed to multiple chemicals and there is a wide range of susceptibility to chemical exposures, it cannot be presumed that any – even low-level – exposures are risk-free. It should be assumed that low levels of exposures are associated with some level of risk, unless there are sufficient data to contradict this assumption.

The NRDC recommendations were not specific to IRIS (IRIS was not mentioned by name in the report), but to EPA and FDA.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IRIS Improvements Accelerate After NAS April 2011 Report
April 2011- Present: Internal EPA meetings and external outreach focused on improving IRIS per NRC recommendations
March 2008: GAO report "Chemical Assessments: Low Productivity and New Interagency Review Process Limit the Usefulness and Credibility of EPA's Integrated Risk Information System."
May 2009: New IRIS process; interagency comments publicly available
March 2010: EPA releases HERO database, improving transparency in EPA health assessments
April 2011: Release of NRC report reviewing EPA's draft IRIS assessment for formaldehyde; IRIS improvements are accelerated.
July 2011: EPA begins providing public responses to major interagency comments
Sept. 2011: EPA releases final IRIS assessment for hexachloroethane, streamlined to reduce text volume by 16%
December 2011: GAO issues a report, "Chemical Assessments: Challenges Remain with EPA's Integrated Risk Information System (IRIS) Program" and notes changes to draft IRIS assessments per NRC recommendations.
2008
2009
2010
2011
2012
Dec. 2009: EPA agrees to take the draft formaldehyde assessment to the NAS for review
June 2010: EPA releases draft IRIS assessment for formaldehyde for public comment and external review. Draft development began in 2008, but Congress asked that EPA wait for NCI studies
July 2011: EPA releases final IRIS assessment for urea, streamlined to reduce text volume by 40%
July 2011: EPA issues IRIS Progress Report, noting progress since May 2009 and outlining plan to respond to NRC recommendations. EPA begins implementing NRC recommendations
November 2011: SAB solicits nominations for experts to sit on a standing SAB Chemical Assessment Advisory Committee
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NAS Recommendations for Developing IRIS Assessments

In their review of the draft formaldehyde IRIS assessment, the NAS provided recommendations for improving the development of draft IRIS assessments, in general. For example, the NAS recommended that EPA:

- Provide a fuller discussion of the methods of the assessment; concise statements of criteria used to exclude, include, and advance studies for hazard evaluation and derivation of toxicity values.
- Clearly articulate the rationale and criteria for screening studies and rationale for selecting studies used to calculate toxicity values.
- Use standardized evidence tables to provide methods and results of studies for all health outcomes.
- Use uniform approaches to evaluate strengths and weaknesses of all critical studies and summarize findings in tables.
- Ensure that weight-of-evidence descriptions indicate the various determinants of weight to promote understanding of what elements were emphasized in synthesizing evidence.
- Rigorously edit documents to reduce the volume of text substantially and address redundancies and inconsistencies.

The NAS did not tell EPA to stop developing IRIS assessments or to stop the IRIS Program until changes were fully implemented.

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New Document Structure

- Concise, rigorously edited assessments
- Preamble to describe methods used
- Evidence tables and exposure-response arrays
- Text to focus on analysis and synthesis
- Standardized weight-of-evidence characterization for all health effects
- Distinct separation of hazard identification and dose-response analysis

Progress in Streamlining IRIS Assessments
Examples from recent draft and final assessments

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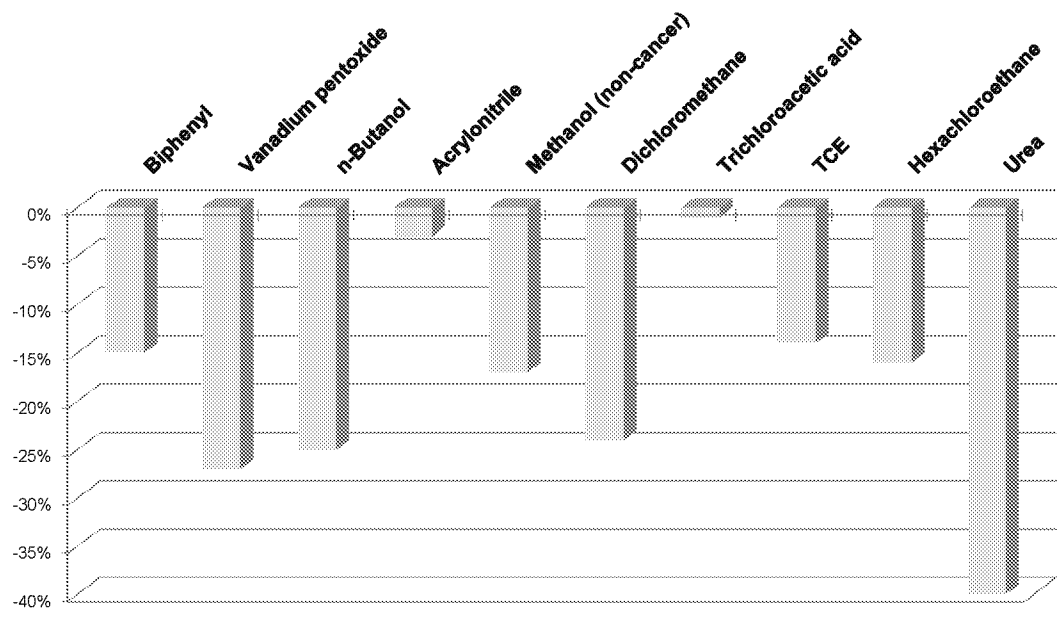

Percent change in number of pages in assessments (not including appendices)

25

Reference Value Array – Example from Dioxin Reanalysis, noncancer

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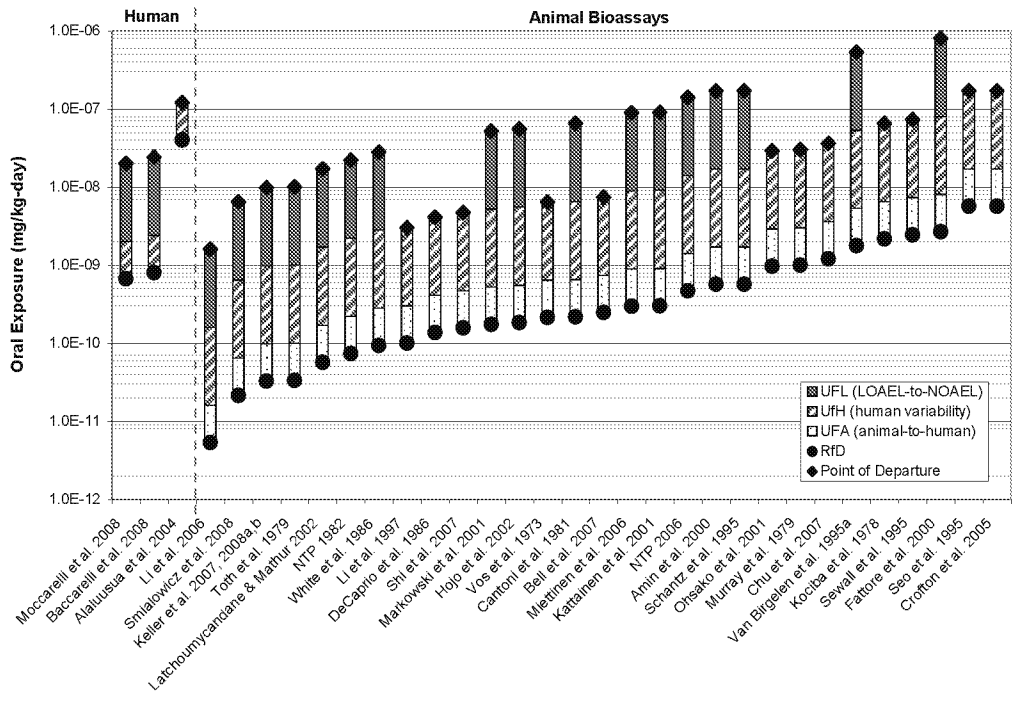

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Reference value array from EPA's May 2010 draft "Reanalysis of Key Issues Related to Dioxin Toxicity and Response to NAS Comments"

Exposure-Response Array – Example

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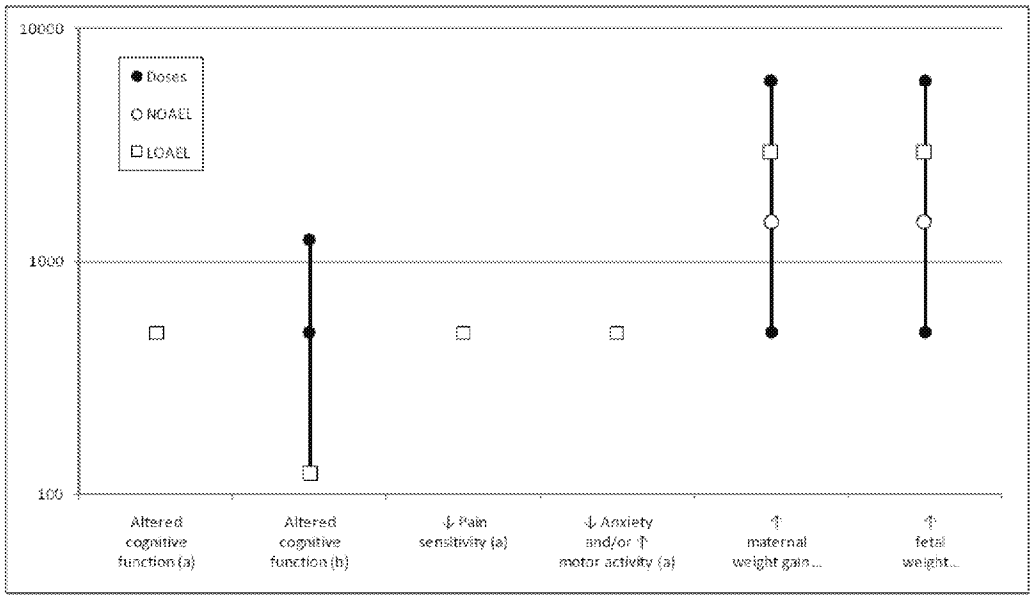

Exposure response array for inhalation exposure to 1,3,5-TMB.

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From the January 2012 Internal Draft IRIS assessment for 1,3,5- and 1,2,4-trimethylbenzenes

IRIS Assessment Preamble

- All new IRIS assessments will include a preamble that is responsive to the NRC recommendations by describing methods and criteria used to develop assessments.

- The preamble discusses the five topics identified in the NRC report in Figure 7-2:
  - Identifying and selecting pertinent studies
  - Evaluating the quality of individual studies
  - Weighing the overall evidence of each effect
  - Selecting studies for derivation of toxicity values
  - Deriving toxicity values

Early Peer Consultation

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Early Peer Consultation

- EPA will hold public peer consultation workshops early in development of some IRIS assessments to enhance input of scientific community.
- Workshop goals will vary depending on chemical (e.g. state-of-the-science for a particular chemical; advice on a cross-cutting scientific issue).
- Summer 2012: EPA will hold a peer consultation workshop on mouse lung tumors as they relate to naphthalene, styrene and ethylbenzene.
- Workshops will be open to public, with opportunity for oral/written comments; details to be announced in Federal Register Notice and on IRIS website.

Weight of Evidence

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Weight of Evidence

- EPA will continue to improve discussion of which criteria were most influential in evaluating weight of scientific evidence supporting choice of toxicity values.
- EPA will hold a public workshop on weight of evidence analysis in 2012; public and stakeholders will be invited. This workshop will:
  - Identify approaches currently in use and compare strengths and limitations.
  - Be open to the public, with opportunity for written and oral comment.
  - Be publicly announced in a Federal Register Notice and on IRIS website.
  - Inform EPA about whether to adopt or adapt existing approaches to weight of evidence classification for use in subsequent IRIS assessments.
- The proposed approach will be externally peer reviewed.

Maintaining Rigorous External Peer Review

United States Environmental Protection Agency

Dedicated Chemical Assessment Advisory Committee

- Under auspices of EPA's Science Advisory Board.
- Will provide advice on draft IRIS Toxicological Reviews and the IRIS Program.
- EPA will consult this panel for:
  - Peer review of select IRIS assessments; and
  - Advice on how the IRIS Program implements the NAS recommendations.
- Federal Register Notice (Nov. 18) soliciting nominations of scientific experts for appointment to this new committee.
- The SAB is currently taking public comment on the proposed nominated panel before assembling the final Chemical Assessment Advisory Committee.
- First organizational meeting expected June 2012; first chemical-specific meeting anticipated August 2012.

Consolidated Appropriations Act of 2012

United States Environmental Protection Agency

Signed into law December 23, 2011; includes direction to EPA about the IRIS Program related to NRC recommendations, stating that EPA shall:

- Incorporate, "as appropriate, based on chemical-specific datasets and biological effects," the NRC recommendations into the IRIS process.
- Include documentation, in draft assessments released in fiscal year 2012, describing how the NRC recommendations were implemented.
- Contract with the National Academy of Sciences (NAS) to conduct up to three reviews of IRIS assessments (one of which must be arsenic) that EPA seeks to make final.
- Issue a progress report to House and Senate Committees on Appropriations and relevant Congressional authorizing committees to describe ongoing implementation of the NRC recommendations for ongoing and new IRIS assessments.

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Summary

- The IRIS Program continues to have one of the most transparent processes in the federal government.
- EPA's Programs and Regions partner with ORD to set the agenda for IRIS.
- Rigorous, open, independent peer review has been and remains the cornerstone of the Program.
- Strengthening the IRIS Program remains a priority.
- Additional changes coming soon include a new document structure, a standing SAB committee, early peer consultation workshops, and a weight-of-evidence workshop.

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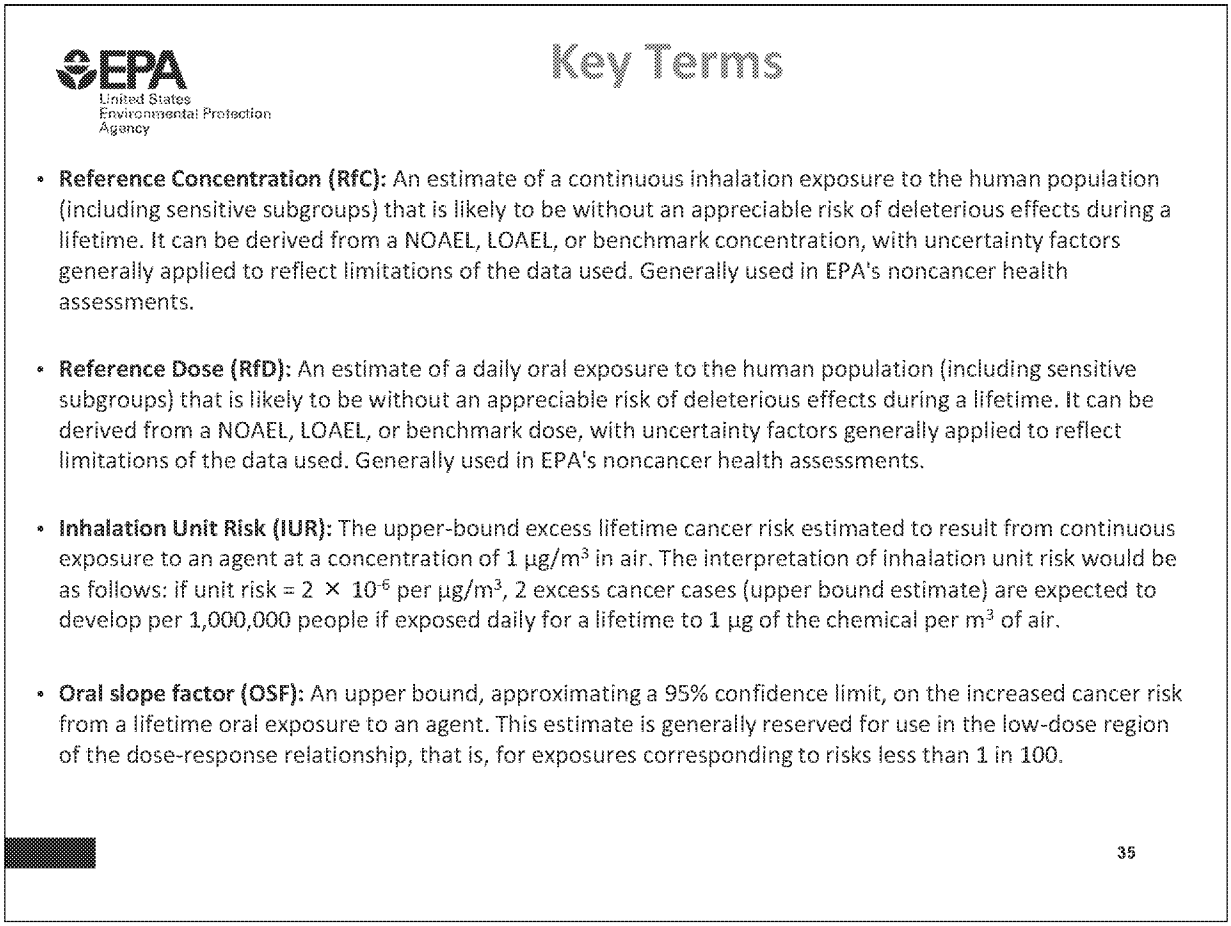
Additional Reference Slides



RfC and RfD are doses, while the oral cancer slope factor and IUR are rates (i.e., increase in risk per unit dose).
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IRIS Process: 2004 to April 2008

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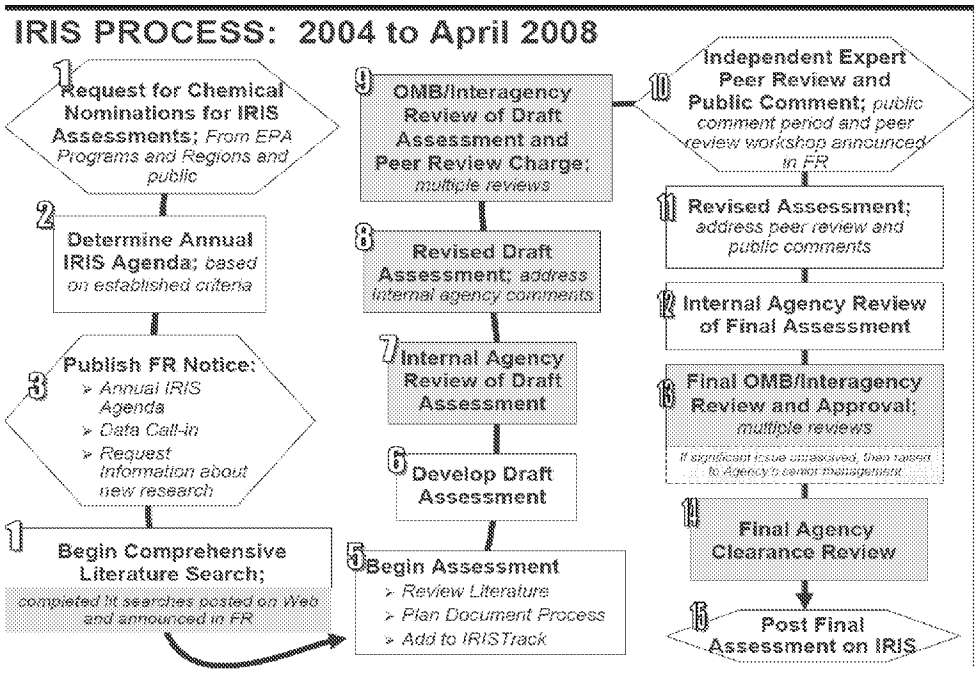
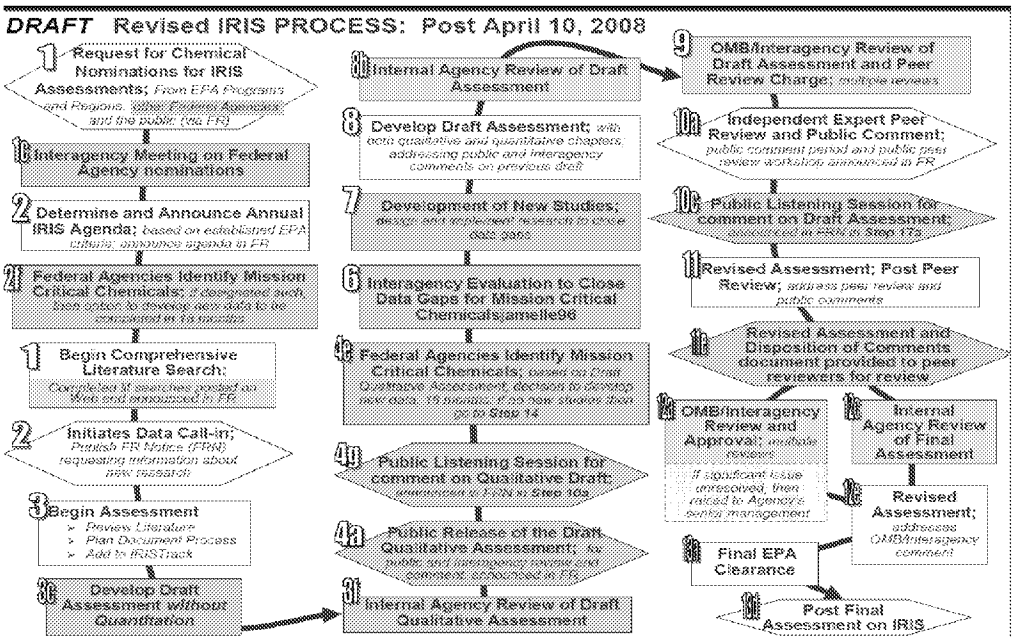


IRIS Process: April 10, 2008 to May 21, 2009

United States Environmental Protection Agency



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Upcoming Final IRIS Assessments for FY2012 – Halogenated Platinum Salts

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Halogenated platinum salts

- Final Agency Review/Interagency Science Discussion are complete; we are finalizing the assessment.
- The assessment focuses on halogenated platinum salts. Vehicles using platinum fuel additives may produce emissions containing soluble platinum with characteristics of halogenated platinum salts.
- Halogenated platinum salts are different from elemental platinum and other platinum compounds; some stakeholders are concerned the assessment will place a stigma on the use of all platinum (e.g., platinum metal in jewelry), resulting in economic and environmental impacts (e.g., on the production and use of catalytic converters).
- The RfC in this assessment will be the most potent non-cancer toxicity value on IRIS.
- Significant stakeholder interest is expected.
- There is an open Request for Correction on the draft assessment.

Upcoming Final IRIS Assessments for FY2012 – Ethylene Oxide

United States Environmental Protection Agency

Ethylene oxide

- Final Agency Review/Interagency Science Discussion are complete; we are finalizing the assessment.
- Ethylene oxide (EtO) is manufactured from ethylene and used as a: chemical intermediate to manufacture ethylene glycol; sterilizing agent for medical equipment; and fumigating agent for spices.
- The assessment concludes that ethylene oxide is "likely to be carcinogenic to humans" based on epidemiological evidence in humans, experimental animal data, and evidence of a mutagenic mode of action.
- EPA's Office of Pesticide Programs (OPP) approved the re-registration of ethylene oxide in 2008 for use as a sterilizing agent for medical and laboratory equipment and a fumigant for spices. OPP is conducting a Special Review of EtO that is currently on hold pending completion of the IRIS assessment. The IRIS Program is working closely with OPP to complete the assessment.
- The assessment will be of interest to industry trade groups (American Chemistry Council and companies that use and manufacture EtO) and may be of interest to FDA since they need to assure sterile medical devices.

Upcoming Final IRIS Assessments for FY2012 – Methanol (noncancer)

EPA United States Environmental Protection Agency

Methanol (noncancer)

- Will soon enter Step 6, Final Agency Review/Interagency Science Discussion.
- In January 2010, EPA released for public comment and external peer review a draft methanol assessment that included both cancer and noncancer effects. The SAB external peer review meeting was postponed due to concerns related to data from the Ramazzini Institute (RI).
- In April 2011, EPA released a separate draft methanol assessment for noncancer only, putting the cancer portion on hold. An external peer review meeting was held in July 2011.
- Methanol is among the highest-ranking production volume chemicals in the world and is used in a variety of commercial and consumer products, including paints, varnishes, antifreeze, windshield washer fluid, and others.
- The Methanol Institute and other industries have expressed concern about EPA deriving an RfD and RfC for methanol because of concerns about RI data (which have no bearing on the noncancer assessment).
- There is an open Request for Correction on the draft assessment.

Additional Draft IRIS Assessment Releases for FY2012

EPA United States Environmental Protection Agency

Draft releases (for public comment and external peer review)

- Ammonia
- Trimethylbenzenes (1,2,4- and 1,3,5-)
- PCBs (noncancer)
- Formaldehyde
- Acrylonitrile
- Benzo(a)pyrene
- Phthalates (6 individual and one cumulative assessment)
- t-butanol

Information about Key Upcoming Draft Assessments

United States Environmental Protection Agency

Ammonia and trimethylbenzenes:

- Anticipated public release of spring 2012.
- These draft assessments will represent a major advancement in implementing the NAS recommendations (using new document structure, preamble, tables, figures, etc.).
- These will be the first draft assessments to be reviewed by the new SAB Chemical Assessment Advisory Committee.
- High external interest is anticipated.

Phthalates:

- Six individual assessments and one cumulative assessment based on common adverse outcome
  - dibutyl phthalate (DBP), di(2-ethylhexyl)phthalate (DEHP), butyl benzyl phthalate (BBP), di-isobutyl phthalate (DIBP), di-isononyl phthalate (DINP), and dipentyl phthalate (DPP)
  - Individual summaries and one cumulative assessment
- Workshop December 2010 to evaluate NAS recommendations related to methods for performing a cumulative assessment for these phthalates
  - Determine which options for conducting a cumulative risk assessment for the phthalates should be included in the assessment and the strengths and limitations of these options.
  - First step in considering risks of exposure to multiple chemicals
  - May serve as a framework for extension to other compounds in the future

Information about Key Upcoming Draft Assessments

United States Environmental Protection Agency

PCBs:

- Anticipated public release of spring 2012; peer review by the SAB.
- Current draft RfD is below average dietary intake.
- High external interest is anticipated.

Hexavalent chromium:

- Reassessment for oral exposure to chromium VI (noncancer and cancer) underwent external peer review in 2011.
- Ongoing research program was presented by stakeholders to the external peer review panel meeting.
- Peer reviewers recommended that EPA wait for the results of the ongoing research.
- EPA announced in February 2012 that the IRIS Program would wait for the soon to be completed peer-reviewed primary research before revising the assessment and that the assessment would also include the inhalation pathway of exposure.
- An updated timeline has been included on IRISTrack with a tentative completion date of December 2014.
- This timeline is in accord with the timeline for the Agency's obtainment of suitable exposure information for decision-making.

Information about Key Upcoming Draft Assessments - Arsenic

United States Environmental Protection Agency

Arsenic

- Efforts to complete a cancer assessment for inorganic arsenic have been ongoing for 14 years.
- Several external reviews have been conducted (NAS, 1999; NAS, 2001; SAB, 2007; SAB, 2011).
- The SAB released their final report in 2011 on the focused peer review of the revisions made in the 2007 draft cancer assessment. A draft IRIS assessment for noncancer effects is under development.
- Consolidated Appropriations Act of 2012 directs EPA to submit an IRIS assessment for cancer and noncancer hazards associated with oral exposure to inorganic arsenic to the NAS for review.
- Proposals for the plan forward have been developed, and include an initial workshop, updating the cancer literature and inclusion of the noncancer endpoints.
- There is an outstanding Request for Correction on the draft IRIS cancer assessment.

Formaldehyde

- Draft assessment released for public review and comment and external peer review by the NAS (June 2010).
- EPA received final NAS review report (April 2011).
- EPA is currently revising the assessment to address the NAS comments.
- A timeline for additional review, including whether a focused peer review is feasible and whether the peer review should be through the SAB or contractor-led, is currently under discussion.